No. 05-608

IN THE

Supreme Court of the United States

MEDIMMUNE, INC.,

Petitioner,

v.

GENENTECH, INC., *et al.*,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY TO BRIEF IN OPPOSITION

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REPLY TO BRIEF IN OPPOSITION

The Federal Circuit after *Gen-Probe*[1] now requires that patent licensees commit a material breach of contract before they can sue under the Declaratory Judgment Act, 28 U.S.C. § 2201, to challenge validity, enforceability, or infringement. Unless material breach has occurred, the Federal Circuit now banishes

[1] *Gen-Probe Inc.* v. *Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir.), *pet'n for cert. dismissed*, 543 U.S. 941 (2004). *Gen-Probe* and the decisions following it contradict prior Federal Circuit law. See *C.R. Bard, Inc.* v. *Schwartz*, 716 F.2d 874, 882 (Fed. Cir. 1983) ("we hold that a patent licensee may bring a federal declaratory judgment action . . . without prior termination of the license"); see also *Gen-Probe Inc.* v. *Vysis*, No. 99-CV-2668H (S.D. Cal. Mar. 12, 2002) ("It is settled law that an effective license between the parties does not preclude federal question jurisdiction over a licensee's declaratory judgment action."), *rev'd*, 359 F.3d 1376 (Fed. Cir.), *pet'n for cert. dismissed*, 543 U.S. 941 (2004) (reprinted in Petition for Certiorari, *Gen-Probe Inc.* v. *Vysis, Inc.*, No. 04-260, at 25a).

such disputes from the avenue of relief Congress provided in the Declaratory Judgment Act. Certiorari is appropriate because the Federal Circuit has acted contrary to the established understanding of Article III and the Declaratory Judgment Act, and also contrary to the policy of the patent laws as held in *Lear, Inc.* v. *Adkins*, 395 U.S. 653 (1969)..

A. "Reasonable Apprehension of Suit."

The Declaratory Judgment Act extends to the limits of Article III. *Ashwander* v. *TVA*, 297 U.S. 288, 325 (1936); see Pet. Cert. 11 n.8. The simple jurisdictional requirement is that there be a dispute as to legal rights that is—as here—"definite and concrete." *Aetna Life Ins. Co.* v. *Haworth*, 300 U.S. 227, 242 (1937).

> "The sole requirement for jurisdiction under the Act is that the conflict be real and immediate, i.e., that there be a true, actual 'controversy' required by the Act."

Cardinal Chem. Co. v. *Morton Int'l, Inc.*, 508 U.S. 83, 96 (1993), quoting *Arrowhead Indus. Water, Inc.* v. *Ecolochem, Inc.*, 846 F.2d 731, 735 (Fed. Cir. 1988).[2]

That constitutional requirement was fully satisfied in this case. Petitioner sought resolution of "a concrete case admitting of an immediate and definitive determination of the legal rights of the parties in an adversary proceeding upon the facts alleged." *Aetna*, 300 U.S. at 241. Respondents have never wavered in asserting that the licensed patent is valid and infringed by petitioner's Synagis®; and petitioner equally has never wavered in disputing those assertions. The fact that petitioner has not in addition committed a material breach does not convert this mature and concrete dispute into what respondents call "a hypothetical" set of facts. Br. Opp. 10, quoting *Aetna*, 300 U.S. at 241.

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[2] Of course no one disputes the familiar proposition, see Br. Opp. 10-11, that if there is no actual controversy, federal courts may not issue advisory opinions as to purely hypothetical situations.

The "reasonable apprehension of suit" formulation, which courts have applied in varying situations, is not an exclusive determinant of Article III jurisdiction in every instance, nor does it overrule this Court's decisions going back to *Aetna*. It is simply a sometimes convenient proxy for the Article III and DJA requirement of "actual controversy." As the First Circuit has explained, "reasonable apprehension of suit"

> "is not the only way to establish the existence of a case for purposes of Article III."

Sallen v. *Corinthians Licenciamentos LTDA*, 273 F.3d 14, 25 (1st Cir. 2001). An actual and concrete dispute as to legal rights between adverse parties satisfies Article III and the Declaratory Judgment Act, whether or not described as "apprehension of suit." *Id.*

The issue presented in the petition is not the phrase "reasonable apprehension of suit." Rather, it is that the Federal Circuit now has *redefined* "reasonable apprehension of suit" —and with it Article III and the statutory term "actual controversy"—to require absolutely that before a patent licensee can seek a declaratory judgment, it must place itself in material breach—and at risk of treble damages, penalties, and injunction—contrary to the Declaratory Judgment Act's central purpose. P.C.A. 5a-6a, citing *Gen-Probe*. But this Court held long ago that a patent licensee should not have to choose between paying "the heavy hand of . . . tribute" or

> "risk[ing] not only actual but treble damages in infringement suits. . . . It was the function of the Declaratory Judgments Act to afford relief against such peril and insecurity."

Altvater v. *Freeman*, 319 U.S. 359, 365 (1943).[3]

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[3] Only by assuming the validity of *Gen-Probe*'s new definition could the Federal Circuit say that "MedImmune concedes that it is free of apprehension of suit." P.C.A. 4a, cited at Br. Opp. 3. MedImmune expressly asserted apprehension that it would be sued for treble damages

B. Conflict With Other Circuits.

The petition discussed a number of decisions in other Circuits that place the Federal Circuit's constitutional interpretation diametrically at odds with the application of Article III and the Declaratory Judgment Act in other courts of appeals. Pet. Cert. 14-16. Several of those decisions the Brief in Opposition does not mention.[4] Others it brushes aside with the comment that "[c]ases concerning 'very likely' breaches are simply not helpful." Br. Opp. 18.

To play down the conflict with other Circuits, respondents rely instead on a long string of opinions that have used the phrase "reasonable apprehension of suit." Br. Opp. 8-9 n.4. But none of the cases respondents cite used the phrase "reasonable apprehension of suit" to mean what the Federal Circuit redefined it to mean in *Gen-Probe* and here: material breach as a precondition to suit. Indeed, not a single one involved an enforceable patent license, or a license of any other kind. Most were ordinary determinations of whether a threat of infringement, not involving a license, was immediate enough or too speculative to be an "actual controversy." Many antedated the Federal Circuit and further confirm, as the petition already has demonstrated, that the law was firmly established that licensees were not required to commit material breach before seeking declaratory relief. Pet. Cert. 13-14.

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and onerous penalties if it ceased to pay royalties—which was what the Federal Circuit then ruled under *Gen-Probe* was no longer jurisdictionally sufficient.

[4] *E.g.*, *Doody* v. *Ameriquest Mortgage Co.*, 242 F.3d 286, 288 (5th Cir. 2001) (DJA authorizes suits "before the dispute grows into a contract violation"); *Continental Cas. Co.* v. *Coastal Sav. Bank*, 977 F.2d 734, 738 (2d Cir. 1992) (DJA "intended to avoid precisely the 'accrual of avoidable damages to one not certain of his rights'"); *ACandS, Inc.* v. *Aetna Cas. & Surety Co.*, 666 F.2d 819, 823 (3d Cir. 1981) (quoting *Continental*); see Pet. Cert. 14-16.

Not only do the opinions respondents cite provide no support for the Federal Circuit rule: several are in fact antithetical to it. In *National Basketball Ass'n* v. *SDC Basketball Club, Inc.*, 815 F.2d 562 (9th Cir. 1987), cited Br. Opp. 9 n.4, the court held that a party to a joint venture agreement could bring an action under the Declaratory Judgment Act without first exposing itself to risk of liability:

> "The . . . alternative formulation of case and controversy would force the NBA to impose a fine or sanction on the Clippers before an action could accrue. *This is the type of Damoclean threat that the Declaratory Judgment Act is designed to avoid.* . . . Since the NBA's 'real and reasonable apprehension' . . . was that any action on the Clippers' move could result in antitrust liability, the case is justiciable."

Id. at 566 (emphasis supplied). Similarly, in *GTE Directories Pub. Corp.* v. *Trimen America, Inc.*, 67 F.3d 1563 (11th Cir. 1995), the court rejected a supposed requirement to risk or incur potential liability:

> "The practical effect of finding no case or controversy in the instant case would be to force GTEDPC to contact Trimen's clients thereby subjecting itself to potential liability before allowing it to receive a declaratory judgment. GTEDPC is not required to take such action for an actual case or controversy to exist."

Id. at 1568.

Crowley Cutlery Co. v. *United States*, 849 F.2d 273, 276 (7th Cir. 1988), quoted at Br. Opp. 11, required simply that there be "an existing legal dispute"—as there is here. In fact, the court's relevant jurisdictional holding (dismissing on other grounds) was that the plaintiff's stated fear of prosecution for importing switchblade knives was sufficient to "satisfy the requirements of Article III." *Id.*

Presented with the exact issue raised here, the Second Circuit held that licensees need not withhold royalty payments, because "such repudiation of the licensing agreement should not be precondition to suit." *Warner-Jenkinson Co.* v. *Allied Chem. Corp.*, 567 F.2d 184, 187 (2d Cir. 1977) (citing "most courts who have considered the issue"). Respondents acknowledge *Warner-Jenkinson* as "arguably . . . disagreeing with the Federal Circuit's decision." Br. Opp. 19.[5] And in *Precision Shooting Equip. Co.* v. *Allen*, 646 F.2d 313 (7th Cir.), *cert. denied*, 454 U.S. 964 (1981), the Seventh Circuit held sufficient under Article III that the licensee alleged "a reasonable apprehension that the patentee will bring an infringement suit against him *if* there is non-compliance with the license." *Id.* at 318 (emphasis supplied); see Pet. Cert. 13. Those jurisdictional principles apply no less in the regional Circuits today. *E.g.*, *Starter Corp.* v. *Converse, Inc.*, 84 F.3d 592, 595 (2d Cir. 1996), cited at Br. Opp. 20 (jurisdiction satisfied based on communication of "intent" "to bring an infringement suit should Starter engage in the sale.").

C. The Federal Circuit's Jurisdictional Rule.

Gen-Probe has declared an absolute jurisdictional rule that hereafter the

> "license, unless materially breached, *obliterated any reasonable apprehension of a lawsuit.*"

359 F.3d at 1381 (emphasis supplied). As the District Court pointedly recognized, until *Gen-Probe*,

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[5] Respondents assert that *Warner-Jenkinson* somehow was challenged *sub silentio* by decisions using the phrase "reasonable apprehension of suit." Br. Opp. 18-19. That is not correct. Moreover, a plaintiff "need not prove that [the defendant] expressly has threatened to take legal action." *Interdynamics, Inc.* v. *Wolf*, 698 F.2d 157, 167 (3d Cir. 1982), cited at Br. Opp. 9 n.4.

> "In the past, the 'actual controversy' requirement has not been interpreted by precluding a licensee from challenging a patent it licenses."

P.C.A. 24a. The Federal Circuit's absolute rule also contradicts this Court:

> "The difference between an abstract question and a 'controversy' contemplated by the Declaratory Judgment Act is necessarily one of degree, and *it would be difficult*, if it would be possible, *to fashion a precise test* for determining in every case whether there is such a controversy."

Maryland Cas. Co. v. *Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941) (emphasis supplied).

Respondents at one point pretend that the Federal Circuit nevertheless "retained the totality-of-the-circumstances test." Br. Opp. 15. That is plainly not so in any meaningful sense. What the Federal Circuit unambiguously held, both in *Gen-Probe* and here, was that "the jurisdictional requirements of a declaratory action are not met when royalties are fully paid to the licensor and there is no ground on which the licensor can cancel the license or sue for infringement." P.C.A. 6a. The Federal Circuit described its mechanical *Gen-Probe* rule as its "synthesis of the totality-of-the-circumstances test for determining whether there is a justiciable controversy." P.C.A. 7a-8a. Citing *Gen-Probe*, the Federal Circuit reiterated that without breach "there is no defaulting licensee and *no possibility of suit*." P.C.A. 6a (emphasis supplied).

On that basis the Federal Circuit in the present case held that "as a licensee in good standing" petitioner "cannot bring a declaratory action to challenge the patent under which it is licensed" because there is "no justiciable controversy." P.C.A. 4a-5a. There has not been a Federal Circuit case since *Gen-Probe* that has held otherwise. The Federal Circuit has followed *Gen-Probe* four times and declined four petitions

for rehearing *en banc*,[6] and the 94 district courts in patent cases are obediently applying, however skeptically,[7] this new Article III jurisdictional rule.

D. *Lear, Inc.* v. *Adkins.*

For several years, the Federal Circuit has been issuing decisions critical of this Court's holding in *Lear*, and seeking every possible way to escape it. See, *e.g.*, *Studiengesellschaft Kohle, m.b.H.* v. *Shell Oil Co.*, 112 F.3d 1561, 1567 (Fed. Cir.) (*Lear* sounds "tones that echo from a past era"), *cert. denied*, 522 U.S. 966 (1997); *Gen-Probe*, 359 F.3d at 1381 ("In several instances, this court has declined to apply the *Lear* doctrine."); cases cited at Pet. Cert. 17-18.

With *Gen-Probe* and the present case, the Federal Circuit now has effectively done away with *Lear* completely for licensees not in material breach. Being unable frontally to overturn this Court's *Lear* holding under the patent laws—which was reiterated in *Cardinal Chem. Co.*, 508 U.S. at 96, 100—it has achieved nearly the same result by an unprecedented rereading of Article III and the Declaratory Judgment Act. Moreover, by invoking the Constitution, it has placed its revival of licensee estoppel beyond the power of

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[6] In *Gen-Probe*; in *MedImmune, Inc.* v. *Centocor, Inc.*, 409 F.3d 1376 (Fed. Cir. 2005), *pet'n for cert. pending* (No. 05-656); in *Metabolite Labs., Inc.* v. *Laboratory Corp. of America Holdings*, 370 F.3d 1354, 1369 (Fed. Cir. 2004), *cert. granted on another question*, 126 S. Ct. 601 (2005) (No. 04-607); and in *Teva Pharmaceuticals USA, Inc.* v. *Pfizer, Inc.*, 405 F.3d 990 (Fed. Cir.) (three judges dissenting), *cert. denied*, 126 S. Ct. 473 (2005).

[7] *E.g.*, P.C.A. 31a ("serious misgivings"), noting that the Federal Circuit now

> "forces licensees to take tremendous risk to challenge a patent, one that some with valid claims will likely be unwilling to take."

P.C.A. 30a.

Congress to correct. The only body in a position effectively to do so is now this Court.

CONCLUSION

For the reasons stated herein and in the petition, certiorari should be granted.[8]

Respectfully submitted,

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[8] Respondents note that some patents can receive narrow reexamination by the U.S. Patent and Trademark Office pursuant to 35 U.S.C. §§ 302 and 311. Br. Opp. 23-24. That very limited procedure, however, is not nearly equivalent to challenge of a patent in an adversarial judicial proceeding, and is limited to prior printed publications and patents. 35 U.S.C. § 302. Petitioner's challenges—based on inequitable conduct, fraud on the Patent Office, lack of adequate support in the patent for the invention, non-infringement, and other fundamental violations—cannot be raised in such a proceeding.